

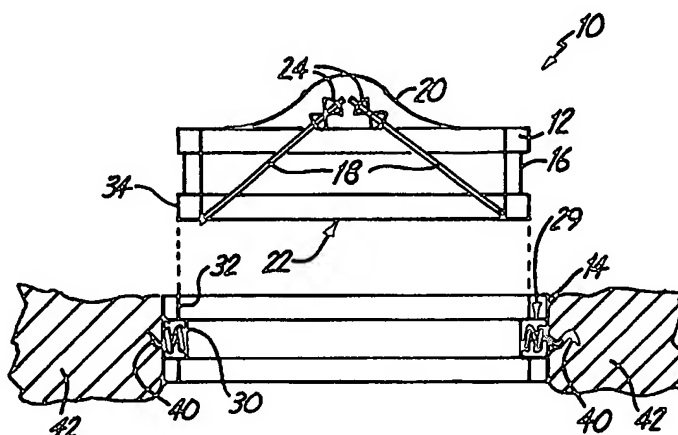
PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61B 17/064, 17/068, A61F 2/24		A1	(11) International Publication Number: WO 99/53845
			(43) International Publication Date: 28 October 1999 (28.10.99)
(21) International Application Number: PCT/US99/08817		(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).	
(22) International Filing Date: 19 April 1999 (19.04.99)			
(30) Priority Data: 09/062,822 20 April 1998 (20.04.98) US 09/203,169 1 December 1998 (01.12.98) US			
(71) Applicant: ST. JUDE MEDICAL, INC. [US/US]; One Lillehei Plaza, Saint Paul, MN 55117 (US).			
(72) Inventors: BUCHANAN, Eric, S.; 4905 Tri Oaks Circle South, Wyoming, MN 55092 (US). ANDERSON, Kimberly, A.; 956 Coneflower Court, Eagan, MN 55123 (US).			
(74) Agents: CHAMPLIN, Judson, K.; Westman, Champlin & Kelly, P.A., International Centre, Suite 1600, 900 Second Avenue South, Minneapolis, MN 55402-3319 (US) et al.		Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>	

(54) Title: DRIVER TOOL FOR HEART VALVE PROSTHESIS FASTENERS



(57) Abstract

A driver tool (210) which drives helical fasteners (214) through a heart valve component (212) into tissue (213). The tool (210) has a tool housing (216) with a distal end (218) coupleable to engage the implanted component (218). A drive shaft (222) at the proximal end of the driver tool (210) couples to a driving force. Multiple driver tips (266) couple to helical fasteners (214) for the heart valve component (212).

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

WO 99/53845

PCT/US99/08817

-1-

DRIVER TOOL FOR HEART VALVE PROSTHESIS FASTENERS**FIELD OF THE INVENTION**

The present invention relates to mechanical heart valve prostheses. More specifically, the invention relates to a driver tool for attaching and implanting heart valve prostheses.

BACKGROUND OF THE INVENTION

Implantable mechanical heart valves are used for replacement of defective valves in hearts of patients. One common method employs a sewing ring or suture cuff which is attached to and extends around the outer circumference of the mechanical valve orifice. The sewing cuff is made of a biocompatible fabric suitable for allowing a needle and suture to pass therethrough. The valves are typically sutured to a tissue annulus that is left when the surgeon removes the existing valve from the patient's heart. The sutures are tied snugly, thereby securing the valve to the heart.

Sewing cuffs are labor intensive, difficult to manufacture and may be difficult to secure to the valve orifice. Further, attaching the suture cuff to the tissue annulus is time consuming and cumbersome. The complexity of suturing requires a patient to be on cardiopulmonary bypass for a lengthy period. It is also desirable to provide a large lumen through the valve orifice relative to the overall valve diameter for blood flow. However, techniques for attaching the sewing cuff to the valve orifice typically require that the area of the valve lumen be reduced to accommodate an attachment mechanism. For example, the sewing cuff is typically retained between two rims of the valve orifice. One of the rims normally defines the outside diameter of the

WO 99/53845

PCT/US99/08817

-2-

valve orifice and thus limits the size of the valve lumen.

Another technique for attaching heart valves uses a series of pins which pierce the tissue annulus of the heart. The pins are crimped or bent, thereby locking the valve to the heart tissue and preventing the valve from separating from the heart. This technique is described in U.S. Patent Nos. 3,574,865 and 3,546,710. Another technique for attaching a prosthetic heart valve to the heart tissue is shown in U.S. Patent. No. 4,705,516 in which an outer orifice ring is sutured to the tissue annulus and an inner orifice ring is then screwed into the outer orifice ring. However, the rings are not locked together and may become unscrewed after extended use.

Implantable heart valves can require fasteners to hold them securely to surrounding tissue in the body. Suturing has been used. However, the use of suturing is time consuming and increases the duration of the implantation surgical procedure. The use of helical fasteners or screws is disclosed in the above cited pending application. However, access one at a time to the multiple helical fasteners used with an implant can be difficult and time consuming. The fasteners face in different directions and a simple tool must be positioned multiple times to approach the implantable heart valve component from several difficult angles around the heart, some of which may be obstructed by adjoining tissue. There is a need for an improved technology for screwing helical fasteners through a heart valve component into a tissue annulus of the heart.

WO 99/53845

PCT/US99/08817

-3-

SUMMARY OF THE INVENTION

The present invention is useful in implanting a prosthetic heart valve in a heart with helical fasteners. The heart valve includes an outer ring for
5 coupling to a tissue annulus of a heart. An inner orifice ring includes an occluding mechanism movable between an open position, which allows blood flow through the lumen, and a closed position which prevents blood flow through the lumen. The inner orifice ring is
10 adapted to be coupled to the outer orifice ring after the outer orifice ring has been attached to the tissue annulus. The outer ring is attached to the tissue annulus by helical screws and is coupled to the inner orifice ring by a snap fit.

15 In the present invention, a driver tool drives multiple helical fasteners simultaneously through the outer ring of a heart valve component into the surrounding tissue annulus of a heart. The driver tool includes a tool housing and has a distal end couplable
20 to engage the heart valve component and a proximal end spaced from the distal end. A drive shaft at the proximal end is couplable to a driving force. A plurality of driver tips extend from the distal end, each driver tip coupling to a helical fastener for the
25 heart valve. A drive train in the tool housing couples to the drive shaft to distribute driving force to each of the driver tips.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is an exploded cross-sectional view
30 of a prosthetic heart valve.

Figure 2 is a cross-sectional view of the heart valve of Figure 1.

WO 99/53845

PCT/US99/08817

-4-

Figure 3 is a perspective view of an attachment mechanism for the prosthetic heart valve of Figures 1 and 2.

Figure 4 is a side cross-sectional view of an
5 implantation tool for implanting the heart valve prosthesis shown in Figures 1 and 2.

Figure 5 is a side cross-sectional view of the tool of Figure 4 in which a holder portion of the tool is moved to an open position.

10 Figure 6 is a side perspective view of an outer orifice ring in accordance with another embodiment.

Figure 7A is a side plan view and Figure 7B is a side cross-sectional view of the outer orifice ring
15 shown in Figure 6.

Figure 8 is a side perspective view of a suture securing tool.

Figure 9 is a perspective view of a holder for use in implanting an outer ring of a heart valve.

20 FIG. 10 is a side cross sectional view of a driver tool engaging a heart valve outer ring and coupled to helical fasteners in accordance with the present invention.

FIG. 11 is a side cross sectional view of a
25 driver tool engaging a heart valve outer ring and coupled to helical fasteners in accordance with the present invention.

FIG. 12 is an enlarged cross sectional view of the distal end of the driver tool of FIGS. 10 or 11.

30 FIG. 13 is an end view of a distal end of the driver tools of FIGS. 10 and 11.

FIG. 14 is a cross sectional view along line 14-14 of FIG. 12.

WO 99/53845

PCT/US99/08817

-5-

FIG. 15 is an enlarged cross sectional view of an alternate distal end of the driver tools of FIGS. 10 and 11.

FIG. 16 is a further enlarged cross sectional view of a portion of the alternate distal end of the driver tool of FIG. 15.

FIG. 17 is an enlarged cross sectional view of an alternate distal end of the driver tools of FIGS. 10 and 11.

FIG. 18 is an enlarged drawing of front and end views of a helical screw fastener with its last coil turned into the center of the coil.

FIG. 19 is an enlarged drawing of a front and an end view of a driver tip for use with the helical screw fastener of FIG. 18.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Heart valve prosthesis 10 shown in Figure 1 includes inner orifice ring 12 and outer orifice ring 14. Figure 1 is a side cross-sectional exploded view of valve 10 and Figure 2 is a side assembled cross-sectional view of valve 10.

Inner orifice ring 12 includes locking recess 16 (or, in another embodiment, a ridge) formed around its outer circumference. Leaflets (or occluders) 18 provide an occluding mechanism and are pivotably coupled to ring 12 at pivot guard 20. Leaflets or occluders 18 move between an open position (not shown) and a closed position as shown in Figures 1 and 2 in which flow of fluid through lumen 22 is blocked. Leaflets 18 rotate within pivots 24 formed in pivot guards 20. In one preferred embodiment, inner ring 12 comprises a prosthetic heart valve available from St. Jude Medical, Inc. of St. Paul, Minnesota, without a sewing cuff

WO 99/53845

PCT/US99/08817

-6-

carried thereon. However, in some embodiments it may be preferable to use a specially designed inner ring 12.

Outer orifice ring 14 includes locking ridge 30 (or, in another embodiment, a recess) formed on an inner annulus circumference thereon. Inner annulus 32 of ring 14 is sized to have approximately the same radius as outer annulus 34 of inner ring 12. Similarly, locking ridge 30 of outer ring 14 substantially conforms to locking recess 16 of inner ring 12. Locking recess 16 and locking ridge 30 cooperate to provide a ring coupling mechanism adapted to couple the outer orifice ring to the inner orifice ring. Outer orifice ring 14 also includes tissue annulus attachment locking mechanism 40 which, in one preferred embodiment, comprises helical screws carried through holes 29 around the circumference of outer ring 14. Other types of attachment mechanisms include staples, pins, rivets, "nails", barbs, hooks, etc. These mechanisms could be coupled to or integral with the outer orifice ring. As illustrated in Figures 1 and 2, locking mechanism 40 attaches to the natural heart tissue annulus 42 of the patient.

In FIG. 3 a perspective view of locking mechanism 40 is shown in greater detail. Locking mechanism 40 is a helical screw preferably made of a biocompatible material. For example, locking mechanism 40 may be formed from a platinum-iridium alloy, MP35N (a wrought cobalt-nickel-chromium-molybdenum alloy), stainless steel, titanium or other biocompatible materials. As shown in Figure 3, tool 44 includes engaging tip 46 which fits into screw head 48. Locking mechanism 40 may be turned by rotating tool 44. In one embodiment, there are between 8 and 16 substantially

WO 99/53845

PCT/US99/08817

-7-

equally spaced locking mechanisms 40 around the circumference of inner orifice ring 12. However, any number may be used. Locking mechanism 40 typically extends between about .050 to about .200 inches into the
5 tissue annulus 42.

Figure 4 is a side cross-sectional view of tool 60 for use in snapping inner ring 12 into outer ring 14 of heart valve prosthesis 10 shown in Figures 1 and 2. Tool 60 includes elongated handle 62 including
10 proximal gripping end 64. Actuator rod 66 extends through a center opening 68 in handle 62. Holder 70 is coupled to a distal end of handle 62. Holder 70 includes moveable half 72A and fixed half 72B coupled at pivot 74. Halves 72 include lower lip 76 adapted to
15 abut outer ring 14. Distal end 80 of actuator rod 66 couples to actuator cable 82 which is connected to half 72A. Spring 84 is coupled to actuator rod 66 and pushes actuator rod 66 in an axial direction away from holder 70 holding halves 72 in the closed position as shown in
20 Figure 4. Rod 66 includes actuator button 90. Proximal end 64 of handle 62 includes handle grip 93.

Orifice pushing mechanism 91 is aligned axially with handle 62 and coupled to handle 62 by threads 92. Mechanism 91 includes gripping portion 94
25 and orifice abutting surface 96. As shown in Figure 4, orifice abutting surface 96 is adapted to abut inner orifice ring 12.

Figure 5 is a side cross-sectional view of a portion of tool 60 showing holder 70 in an open position
30 in which half 72A is rotated about pivot 74. In this position, heart valve prosthesis 10 is freed from holder 70 such that heart valve prosthesis may be selectively removed from, or engaged with holder 70.

WO 99/53845

PCT/US99/08817

-8-

In operation, pressure is applied to actuation button 90 while grasping handle grip 93. This causes actuator rod 66 to move downward, towards the distal end of tool 60 whereby cable 82 causes half 72A to rotate about pivot 74. When pressure is released from actuator button 90, spring 84 pushes actuator rod 66 in a direction away from holder 70 such that half 72A is moved back into a closed position by cable 82 as shown in Figure 4. After outer orifice ring 14 has been attached to the natural tissue annulus of the patient's heart, tool 60 containing pre-loaded ring 12 is inserted through implantable ring 14 by depressing actuator button 90. This engages lip 76 under ring 14. Mechanism 94 is then rotated whereby lip 76 and surface 96 work in opposing directions such that no axial force is applied to helical screws 40 or the patient's tissue annulus. Outer orifice ring 14 is held against lower lip 76 such that a relative pressure is applied between rings 12 and 14. This causes locking ridge 30 to seat within locking recess 16. When inner ring 12 has been "snapped" in place with ring 14, ring 12 prevents locking mechanisms 40 from unscrewing or disengaging. Force may then be applied to actuator button 90 such that half 72A of holder 70 rotates as shown in Figure 5 so that tool 60 may be removed from prosthesis 10.

Figure 6 is a perspective view of outer orifice ring 100 in accordance with another embodiment which is coupled to suture cuff 102. In the embodiment of Figure 6, ring 100 includes a plurality of suture holes 104 formed therein for receiving sutures 106. Further, the inner annulus of ring 100 includes suture receiving groove 108. Figure 7A is a side plan view of outer ring 100 and Figure 7B is a side cross-sectional

WO 99/53845

PCT/US99/08817

-9-

view of outer ring 100. As shown in Figure 7A, the outer annulus of ring 100 includes cuff retaining grooves 110 formed therein. In one preferred embodiment, O-rings 101 are provided to prevent leakage
5 between the orifice rings as shown in Figure 7B. Retaining sutures are wound circumferentially through cuff 102 and within cuff retaining grooves 110 binding or clamping cuff 102 to ring 100.

Ring 100 is sutured to tissue annulus 42 using
10 sutures 106 which extend radially through cuff 102 and suture holes 104. Preferably, sutures 106 are metal sutures of a biocompatible material such as stainless steel. After the sutures 106 are threaded through the patient's natural tissue annulus and outer orifice ring
15 100, the surgeon secures the suture using knots 114 which may be formed by twisting the suture 106 as shown in Figure 6. Excess suture material is then trimmed and knots 114 are folded into suture grooves 108.

Figure 8 is a side perspective view of a
20 suture securing tool 130 for use in twisting sutures 106 shown in Figure 6. Tool 130 includes elongated body 132 carrying shaft 134 therethrough between an actuator 136 and a hook 138. Spring 140 pushes on end cap 144 and body 132 such that hook 138 presses against end cap 142.
25 By pressing on actuator 136, hook 138 may be extended to hook both ends of suture 106. When actuator 136 is released, suture 106 is trapped between hook 138 and cap 142. Tool 130 is then rotated to twist sutures 106 together forming twisted knots 114 shown in Figure 6.

30 Following implantation of ring 100 into the tissue annulus 42, inner orifice ring 12 as shown in Figure 1 is coupled to ring 100 as described with respect to Figures 1-5.

WO 99/53845

PCT/US99/08817

-10-

Figure 9 is a perspective view of implantation tool 150 for use in implanting orifice ring 100. Tool 150 includes legs 152 having coupling tips 154 which are configured to couple to ring 100. Tool 150 may be used
5 by the surgeon to hold ring 100 during suturing such that force may be applied to ring 100. Tips 154 may be fit into suturing grooves 108. Tool 150 includes handle attachment opening 156 which may be used to selectively engage an elongated handle (not shown). Opening 156 can
10 be as shown or can be a threaded hole, a snap fit hole or other opening adapted to selectively engage an elongated handle.

In FIG. 10, driver tool 210 is shown engaging outer ring 212 of a two piece prosthetic heart valve.
15 Driver tool 210 couples to helical screw fasteners 214 which pass through holes in outer ring 212. Helical fasteners 214 can be any fastener that advances along its central axis by being turned about that axis, i.e., anything that goes in by twisting, such as a screw.
20 Helical screw fasteners 214 attach outer ring 212 to tissue annulus 213 during an implantation procedure using driver tool 210. Driver tool 210 includes tool housing 216, which is generally cylindrical in shape, or round in cross section, and extends from distal end 218,
25 which engages outer ring 212, to proximal end 220 spaced away from the distal end 218. Drive shaft 222 at proximal end 220 has a handle 224 that can receive a twisting or driving force for transmission to helical screw fasteners 214. Handle 224 can also be actuated or
30 pulled away from the proximal end 220 to disengage driver tool 210 from helical screw fasteners 214.

In FIG. 10, handles 226, 228 project laterally from proximal end 220. Handles 226, 228 can be manually

WO 99/53845

PCT/US99/08817

-11-

squeezed together to retract or disengage driver tool 210 from outer ring 212. When handles 226, 228 are squeezed together, tool housing 216 slides relative to tube 232. Handles 226, 228 pivot on pin 227. Handle 226
5 is rigidly coupled to tube 232. Handle 228 has slot 229 engaging a pin in tool housing 216. When handles 226, 228 are squeezed together, tool housing 216 moves toward outer ring 212 while other parts of drive tool 210 remain stationary relative to handle 226. Tool housing
10 216 pushes outer ring 212 away from tool 210, releasing outer ring 212 from tool 210 when handles 226, 228 are squeezed together. Spring 225 maintains handles 226 and 228 in the open or spread apart position and prevents accidental dislodgement of ring 212.

15 As an alternative to the handles 226, 228 of FIG. 10, a release button, along with additional springs can be disposed on the proximal end of tool 210. With this alternative, when the installation of helical fasteners 214 is complete, the release button can be
20 pressed, releasing a catch to retract driver tool 210 from outer ring 212.

In FIG. 11, another alternative embodiment of a tool 211 is shown where there are no handles 226 and 228 as in FIG. 10, and spring 225 prevents accidental
25 dislodgement of ring 212 while the health professional grasps tool housing 216. In FIG. 11, components which are similar to those in FIG. 10 are identified with the same reference numerals used in connection with the description of FIG. 10.

30 In FIG. 11, after helical screw fasteners 214 are driven in by tool 211 in the same manner that helical screw fasteners 214 are driven in by tool 210 (FIG. 10), the handle 224 is lifted or pulled up

WO 99/53845

PCT/US99/08817

-12-

relative to tool housing 216 while the surgeon holds tool housing 216. This lifting action first lifts drive shaft 222, compresses spring 272, thereby disengaging helical screw fasteners 214 from the flexible shafts 262 (FIG. 12) of the tool 211. When spring 272 is fully compressed, lifting force is transferred through the compressed spring 272 to tube 232. When the handle is lifted further, tube 232 lifts relative to tool housing 216, compressing spring 225 while tube 232 remains in contact with outer ring 212. Spring 225 is made stiffer than spring 272 so that the flexible shafts 262 (FIG. 12) disengage from the helical screw fasteners 214 before the tube 232 lifts to release outer ring 212 from tool 211. Tool housing 216 moves toward outer ring 212 while other parts of driver tool 211 retract or move away from outer ring 212. The tool 211 is thus fully disengaged from outer ring 212 and helical screw fasteners 214 after use.

In FIG. 12, distal end 218 is shown in more detail. At distal end 218, cylindrical end 234 of tool housing 216 abuts outer ring 212. Struts 236 of tube 232 extend beyond cylindrical end 234 to engage outer ring 212 with a snap fit between groove 238 of struts 236 and locking ridge 240 of outer ring 212. Outer ring 212 is thus retained securely on distal end 218. Helical screw fasteners 214 pass through holes 242 in outer ring 212 and into tissue annulus 213. In one embodiment, there are approximately eight to sixteen helical fasteners although any number can be used, each passing through a separate hole 242 in outer ring 212. Helical screw fasteners 214 can be formed of metal wire compatible with implantation, and have a hub portion 244 which is wound in a polygonal shape, typically a

WO 99/53845

PCT/US99/08817

-13-

hexagon, and the remainder 246 of the helical fastener is wound in a helix with a sharp point 247 at the end. In another embodiment, the last coil of the hub portion 244 turns into the center of the coil (as described later in FIGS. 18-19).

In FIG. 12, drive shaft 222 couples to drive train 250. Drive shaft 222 may be narrowed to form a gear shaft 252 on its end. Gear plate 254 is assembled on gear shaft 252 so that gear shaft 252 is free to spin. Gear 256 is attached to gear shaft 252 so that gear shaft 252 drives gear 256. Satellite gears 258 are assembled on plate 254 with gear hubs 259 extending through holes in plate 254 so that they engage or mesh with gear 256. Plate 261 is also assembled onto gear shaft 252 with gear hubs 257 extending through holes in plate 261 so that gear shaft 252 is free to spin. Retaining ring 260 is then attached to gear shaft 252 to keep gears 256 and satellite gears 258 caged between gear plates 254, 261. Gear plates 254 and 261 are provided with multiple tabs 263 which are shaped to mate with slots 265. This arrangement prevents drive train 250 from rotating within tube 232 when drive shaft 222 is rotated. Satellite gears 258 are coupled to flexible shafts 262 which extend to helical screw fasteners 214. There are multiple satellite gears 258 and multiple flexible shafts 262, however, for clarity only two of each are illustrated in FIG. 12. In one embodiment, if a second gear 256 is provided to drive some of the fasteners. For example, eight shafts 262 could be driven by gear 256 and a second gear (not shown) located above gear 256 could drive eight more shafts 262 which extend vertically through the spaces shown in Figure 14. Flexible shafts 262 pass through holes in plate 264 and

WO 99/53845

PCT/US99/08817

-14-

in housing 270. Plate 264 and housing 270 are fixed relative to tube 232 and retain flexible shafts 262 in a favorable orientation to transmit twisting motion from the vertical axis of drive shaft 222 to the axis of each

5 helical screw fastener 214. With the satellite gears 258 held in relatively fixed locations relative to tube 232, when drive shaft 222 is twisted relative to tube 232, gear 256 drives satellite gears 258 so that they distribute twisting motion to all eight, or more,

10 flexible shafts 262 simultaneously. Flexible shafts 262, in turn, couple this twist or drive to the helical screw fasteners 214 (only two are shown in FIG. 12). Driver tips 266 on the ends of flexible shafts 262 are shaped to engage the hub portions 244 of helical screw

15 fasteners 214. Typically, driver tips 266 have a hexagonal, square or cylindrical slotted shape and slidably engage a correspondingly hexagonal or square or cylindrical slotted hub shape of helical screw fasteners 214 to transmit torque. Torsional drive is

20 thus distributed from drive shaft 222 (or handle 224) through drive train 250 to drive helical screw fasteners 214 into tissue annulus 213. Helical screw fasteners 214 advance at approximately right angles to the hand twisting motion and at approximately right angles to

25 tool housing 216. Driver tool 210 is inserted in a convenient straight direction down the aorta toward the tissue annulus 213, avoiding having to approach individual helical screw fasteners 214 at awkward or difficult angles and at different radial directions.

30 All of helical screw fasteners 214 advance simultaneously, avoiding delay in completing the implantation.

WO 99/53845

PCT/US99/08817

-15-

In FIG. 12, cylindrical housing 270 is snap fit in tube 232 and serves as a guide for flexible shafts 262, which reduces binding or tangling of flexible shafts 262. Compression spring 272 presses drive train 250 toward distal end 218 to keep driver tips 266 engaged with helical screw fasteners 214. Handle 224 (FIG. 10) can be pulled away from tool housing 216, compressing spring 272 and moving drive train 250 away from distal end 218. When drive train 250 is moved away from distal end 218, driver tips 266 are slid out of or decoupled from helical screw fasteners 214.

In FIG. 13, an enlarged end view of distal end 218 is shown. In FIG. 13, outer ring 212 has been omitted from the drawing for clarity. End 234 of tool housing 216 is generally cylindrical in shape and houses tube 232 which, in one embodiment, has four struts 236 extending from it. Flexible shafts 262 pass through holes 271 in cylindrical housing 270 and couple with hub portions 244 of helical screw fasteners 214. Helical screw fasteners 214 have a helical portion 246 for engaging tissue. Helical portion 246 also couples with the holes 242 in outer ring 212 (FIG. 12) such that helical screw fasteners 214 are self-advancing when twisted about their central axis. Hub portion 244 of helical screw fasteners 214 slides along driver tips 266 to accommodate the advancing motion. This arrangement keeps the helical screw fasteners 214 retained to the tool 210, preventing the fasteners from becoming prematurely detached from the tool. In one embodiment, shafts 262 extend directly in a radial direction or bend to go to a drive tip 266 at a different location due to space limitation in housing 270. In FIGS. 10-13 all of

WO 99/53845

PCT/US99/08817

-16-

the helical screw fasteners 214 can be advanced simultaneously into tissue when handle 224 is twisted relative to tool housing 216. Each flexible shaft 262 turns or bends in a different radial direction.

5 In FIG. 14, internal construction of drive train 250 is shown. FIG. 14 is a sectional view along line 14-14 of FIG. 12. In this embodiment, gear 256 is shown attached to gear shaft 252 and engaging all (e.g. eight or more) satellite gears 258. Gears 256, 258 are
10 spur gears which mesh with each other as shown only partially at 274. The satellite gears are attached to flexible shafts 262 which serve as axles for the satellite gears 258. Drive train 250 is housed within tube 232 which, in turn, is housed in tool housing 216.
15 The use of flexible shafts permits coupling around sharp, approximately right angle turns with multiple radial directions of drive for the multiple helical fasteners.

 The tissue annulus of the heart has been
20 prepared to receive the heart valve prosthesis pursuant to techniques known in the art. Driver tool 210 has been preloaded with outer ring 212 snapped on its distal end 218 and helical screw fasteners 214 inserted in outer ring 212 and coupled to driver tips 266. Distal
25 end 218 is then advanced toward prepared tissue annulus 213 until outer ring 212 is aligned within the tissue annulus. Handle 224 is twisted to advance helical screw fasteners 214 into the tissue annulus. When outer ring 212 is attached by helical screw fasteners 214 to the
30 tissue annulus, handle 224 is lifted relative to tool housing 216. This compresses spring 272 and disengages driver tips 266 from helical screw fasteners 214 if they have not already been disengaged by the advance of the

WO 99/53845

PCT/US99/08817

-17-

helical fasteners. Handles 226 and 228 are squeezed together, unsnapping outer ring 212 of the heart valve from the tool 210. The tool 210 is removed, leaving outer ring 212 attached to the tissue annulus of the heart by multiple helical fasteners.

In FIGS. 15 and 16, an alternative embodiment 300 of the distal end of the driver tool shown in FIGS. 10 and 11 is shown. In Figure 15, drive shaft 322, corresponding to drive shaft 222 in FIGS. 10 and 11, has a tapered portion 302 and a splined tip 304 at the distal end. The splined tip 304 engages a central hub 306 of a turntable 308 for rotating the turntable 308. Turntable 308 has a circular gear rack 310 spaced radially outward from the central hub 306. A plurality of spur gears 312 engage the circular gear rack 310 with loose tolerances, allowing for any misalignment between the spur gears 312 and the turntable. Each spur gear 312 has a hub 314 surrounding a throughhole 316 along a central axis of spur gear 312. Each hub 314 is flared or swaged outwardly to secure it to mounting tube 318 such that it is free to spin when driven by circular gear rack 310. Turntable 308 is free to spin in a circular groove 309 formed on the end of mounting tube 318. Each throughhole 316 is shaped to receive and loosely engage a driver tip 324. When driver tips 324 are hexagonal, then throughhole 316 has a corresponding hexagonal shape and is slightly larger than driver tip 324. A spring arrangement 326 coupled to the plurality of driver tips 324 provides axial force to the driver tips 324 for driving helical fasteners 214. Turntable 308 and spur gears 312 comprise a drive train for driving the driver tips 324. Spring arrangement 326 comprises a plurality of springs 330 which can be formed

WO 99/53845

PCT/US99/08817

-18-

from flat strips of spring steel or other suitable material. Each spring 330 is attached to mounting tube 318 with a fastener 339. Each spring is also attached to a driver tip 324 with a fastener 335 so that driver tip 324 rotates easily on fastener 335 when it is driven by spur gear 312. Each spring 330 engages tapered portion 302 at contact point 332. When drive shaft 322 is down (as illustrated in FIG. 15) the spring arrangement 326 applies a radially outward force to the driver tips assisting with engagement of tissue 334. When drive shaft 322 is lifted up, the contact points 332 engage a narrower cross-section 333 of the tapered portion 302, resulting in a radially inward retraction force on the driver tips 324. Also, when drive shaft 322 is lifted, the turntable 308 disengages from spline 304, allowing the turntable 308 to rotate easily, which facilitates disengagement of driver tips 324. Drive shaft 322 is held in a position for driving by coil spring 336, which is compressed between lip 337 on driveshaft 322 and tube 232. When drive shaft 322 is lifted, spring 336 is compressed first to provide disengagement, and then as drive shaft 322 is lifted further, fully compressed spring 336 transfers lifting force to tube 232, and secondly then, spring 225, which is stiffer than spring 336, is compressed to allow disengagement of struts 236 from protruding ring 240 of outer ring 212.

In the embodiments shown in FIG. 15, the springs 330 can be assisted by additional coil springs secured at location 331, if desired.

In FIG. 17, a further embodiment 350 is shown which is similar to the embodiment shown in FIGS. 15-16, except that the gears 352 are beveled gears and the

WO 99/53845

PCT/US99/08817

-19-

circular gear rack 354 is correspondingly beveled to engage the beveled gears 352. Parts in FIG. 17 which are similar to those in FIGS. 15-16 have the same reference numbers that are used in FIGS. 15-16.

5 In the embodiments shown in FIG. 17, the springs 330 can be assisted by additional coil springs secured at location 331, if desired.

 In FIG. 18, a further preferred embodiment of a helical screw fastener 400 is shown, and a
10 corresponding driver tip 402 is shown in FIG. 19. Helical screw fastener 400 has a hub 404 which includes a last coil which turns into the center of helical screw fastener 400 to form a drive lug 406 which can receive a torsional force. Helical screw fastener 400 has a
15 helical main body 408 ending in a sharp point 410 for engaging a tissue annulus such as tissue annulus 213 of FIG. 12. The driver tip 402 of FIG. 19 includes a slot 420 with a slot base 422 for slidably engaging drive lug 406. The driver tip 402 includes a round shaft 424
20 which slidably engages the main body 408 of helical screw fastener 400. The driver tip 402 also includes a shoulder 426 which, along with the slot base 422 provides an axial driving force to helical screw fastener 400, urging the sharp point 410 toward the
25 tissue annulus 213 of FIG. 12. Preferably, helical screws 214 may be coupled with outer ring 212 such that they are self advancing, thereby needing no axial driving force and simply advance into tissue annulus 213 as they are turned. Helical screw fastener 400 and
30 driver tip 402 can be used in the tools shown in FIGS. 10-17.

 For convenience, a driver tool 210 as shown in any of FIGS. 10-17, outer ring 212 and multiple helical

WO 99/53845

PCT/US99/08817

-20-

screw fasteners 214 are provided assembled in a package as a sterilized kit. The tool is preloaded by having outer ring 212 snapped in place on the distal end, helical fasteners preloaded in holes in the outer ring and the driver tips coupled to the helical fasteners.

Preferably, the rings set forth herein are formed of biocompatible materials. The outer ring is generally made of material more flexible than the inner ring, such as polyethylene terephthalate (PET), polyetheretherketones (PEEK), ultrahigh molecular weight polyethylene, Nitinol® (a nickel-titanium alloy), and polyurethane. The inner ring is made preferably of a material more rigid than the outer ring such as titanium, MP35N (wrought cobalt-nickel-chromium-molybdenum alloy), ceramic, Elgiloy® (cobalt-chromium-nickel-molybdenum iron alloy), pyrolytic carbon or other rigid polymers for the inner ring. The particular shapes of the orifice rings and attachment mechanisms may be modified as appropriate. The ring coupling mechanism for coupling the two rings may be any mechanism as desired and is not limited to the particular "snap" coupling techniques set forth herein. For example, the coupling techniques may include screws, wires, bayonet locking mechanism, and nails which extend axially and engage the rings. Further, the configuration of the inner orifice ring and its occluding mechanism may be other than those set forth herein.

WO 99/53845

PCT/US99/08817

-21-

Implantation time is short and relatively simple implantation techniques can be used. Further, the angular positioning of the leaflets in the inner ring is easily accomplished by rotating the inner ring with respect to the outer ring. The invention allows surgical access to subvalvular features prior to coupling the inner ring to the outer ring without the possibility of damaging the occluding mechanism, for example. The inner valve ring can be removed and replaced without excising the entire prosthesis. The complexity of surgery is reduced because manual suturing may not be required. The area of the lumen is increased over typical prior art designs and a lower profile results because the cuff attachment mechanism requires less area. With the inner ring coupled to the outer ring, the outer ring attachment mechanisms are prevented from "backing out" and completely shielded from blood flow where they could otherwise initiate formation of thrombus. Any type of occluding mechanism may be used and the attachment mechanism may be integral with the ring body. The invention also eliminates suturing such that the implantation procedure is faster. Further, there are no suture tails which could lead to thrombus formation. The invention is also useful in minimally invasive surgery because the attachment is with a single elongate tool which can be placed through a trocar in the patient and the entire valve attached in a single step.

The component parts of tools depicted in FIGS. 10-17 can be constructed of biocompatible polymers such as polyurethane, delrin, polysulfone, of metals such as stainless steel, or of other biocompatible materials. Gears are preferably constructed of nylon, teflon or

WO 99/53845

PCT/US99/08817

-22-

stainless steel. The completed tool or kit can be gamma sterilized and disposable, if desired. Flexible shafts can be formed of stainless steel and coated with nylon or teflon for lubricity. Helical screw fasteners can be
5 made of platinum-iridium alloy, MP35N (a wrought cobalt-nickel-chromium-molybdenum alloy), stainless steel, titanium or other biocompatible materials. If desired, an electric motor can be used to provide the torsional force rather than manually twisting a handle.

10 Although the present invention has been described with reference to preferred embodiments, workers skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the invention.

15

WO 99/53845

PCT/US99/08817

-23-

WHAT IS CLAIMED IS:

1. A driver tool for a heart valve prosthesis component for driving helical fasteners through the heart valve prosthesis component into a tissue annulus
5 of the heart, comprising:
 - a tool housing having a distal end couplable to engage the heart valve prosthesis component and a proximal end spaced away from the distal end; and
 - 10 a drive train mounted in the tool housing having a drive shaft at the proximal end couplable to a driving force and a plurality of driver tips at the distal end couplable to the helical fasteners
15 in the heart valve prosthesis component, the drive train distributing the driving force to each of the driver tips.
2. The driver tool of claim 1, further comprising:
 - 20 a first handle extending from the proximal end and manually actuatable to couple a first actuation motion; and
 - a disengagement mechanism in the tool housing receiving the first actuation motion and
25 disengaging the driver tips from the helical fasteners responsive to the first actuation motion.
3. The driver tool of claim 2, further comprising:
 - 30 a second handle extending from the proximal end and manually actuatable to couple a second actuation motion; and

WO 99/53845

PCT/US99/08817

-24-

5 a decoupling mechanism in the tool housing
 receiving the second actuation motion
 and decoupling the driver tool from the
 heart valve prosthesis component
 responsive to the second actuation
 motion.

4. The driver tool of claim 1, wherein the drive
train further comprises flexible shafts coupling the
driving force to the driver tips.

10 5. The driver tool of claim 4, wherein the
flexible shafts make a turn to engage the driver tips.

6. The driver tool of claim 5, wherein the
flexible shafts make turns in a different radial
direction for each flexible shaft.

15 7. The driver tool of claim 1 wherein the drive
train further comprises:

 a turntable with a central hub coupled to the
 drive shaft and a circular gear rack
 spaced radially outward from the central
20 hub;

 a plurality of gears engaging the circular gear
 rack, each gear having engaging a driver
 tip.

8. The driver tool of claim 7 further comprising:
25 a spring arrangement coupled to the plurality of
 driver tips to provide axial force to
 the driver tips.

9. The driver tool of claim 8 wherein the drive
shaft has a tapered surface coupled to the spring
30 arrangement controlling the axial force to the driver
tips.

10. The driver tool of claim 7 wherein the
plurality of gears are beveled.

WO 99/53845

PCT/US99/08817

-25-

11. The driver tool of claim 1 wherein the helical fasteners are self-advancing.
12. The driver tool of claim 1 wherein the drive train comprises a central gear coupled to the drive shaft and
5 a plurality of satellite gears engaging the central gear and coupled to the driver tips.
13. A driver tool for driving helical fasteners through a heart valve component into tissue, comprising:
10 a tool housing having a distal end couplable to engage the heart valve component and a proximal end spaced away from the distal end;
a drive shaft extending from the proximal end, the drive shaft being twistable by
15 a twisting force;
a plurality of driver tips extending from the distal end, each driver tip couplable to a helical fastener for the heart valve component; and
20 a drive shaft coupled to a drive handle and extending into the tool housing;
a drive train in the tool housing coupling the twisting from the drive shaft to the driver tips.
- 25 14. A method of attaching an outer ring of a heart valve prosthesis component into a tissue annulus of a heart with helical fasteners, comprising:
providing a driver tool which has a handle
30 extending from a drive shaft on a proximal end for distributing drive to multiple driver tips on a distal end;
attaching the outer ring of the heart valve prosthesis component to the distal end;

WO 99/53845

PCT/US99/08817

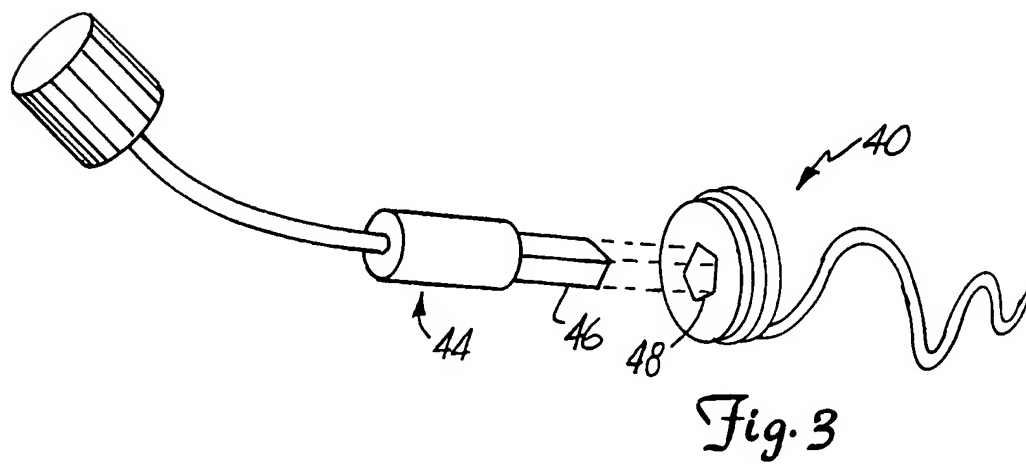
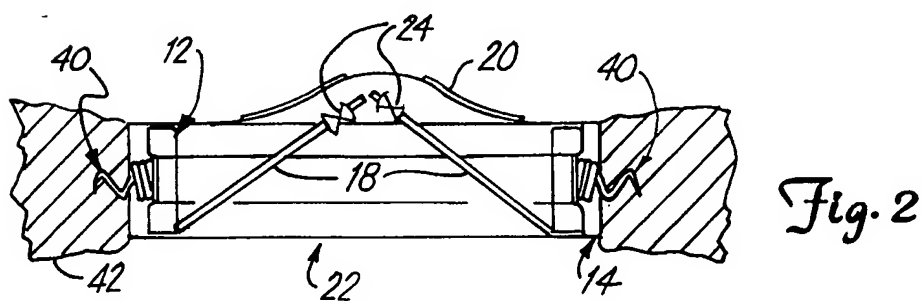
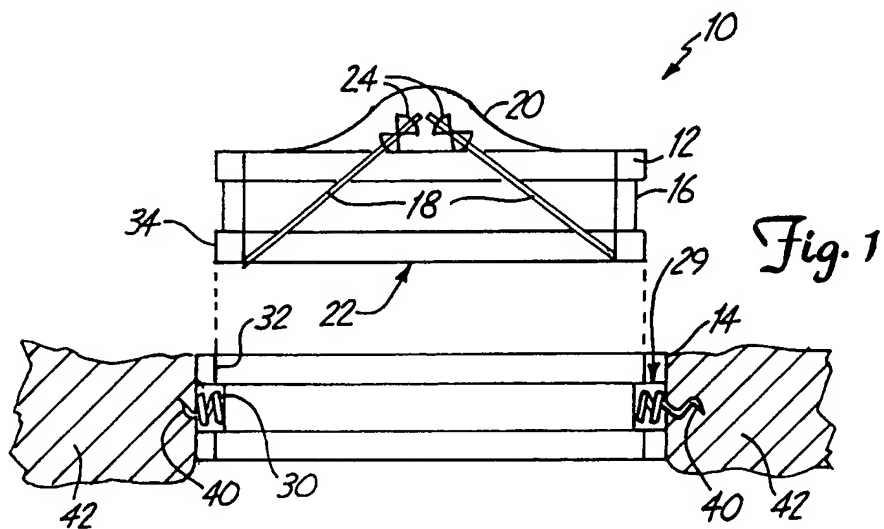
-26-

- placing the multiple helical fasteners on the multiple driver tips and passing them through the outer ring of the heart valve prosthesis component;
- 5 placing the outer ring into the tissue annulus of the heart
- driving the multiple helical fasteners into the annulus of the heart by twisting the drive shaft; and
- 10 removing the driver tool from the outer ring, leaving the outer ring attached to the tissue annulus.
15. A kit for attaching a heart valve prosthesis component to an annulus of tissue in a heart,
- 15 comprising:
- an outer ring of a heart valve prosthesis component;
- a driver tool having a handle extending from a drive shaft on a proximal end and distributing drive to a plurality of driver tips on a distal end of the driver tool, the distal end being removably attached to the outer ring of the heart valve prosthesis; and
- 20
- 25 a plurality of helical fasteners passing through the outer ring of the heart valve prosthesis, each one of the helical fasteners removably coupling to one of the plurality of driver tips.

WO 99/53845

PCT/US99/08817

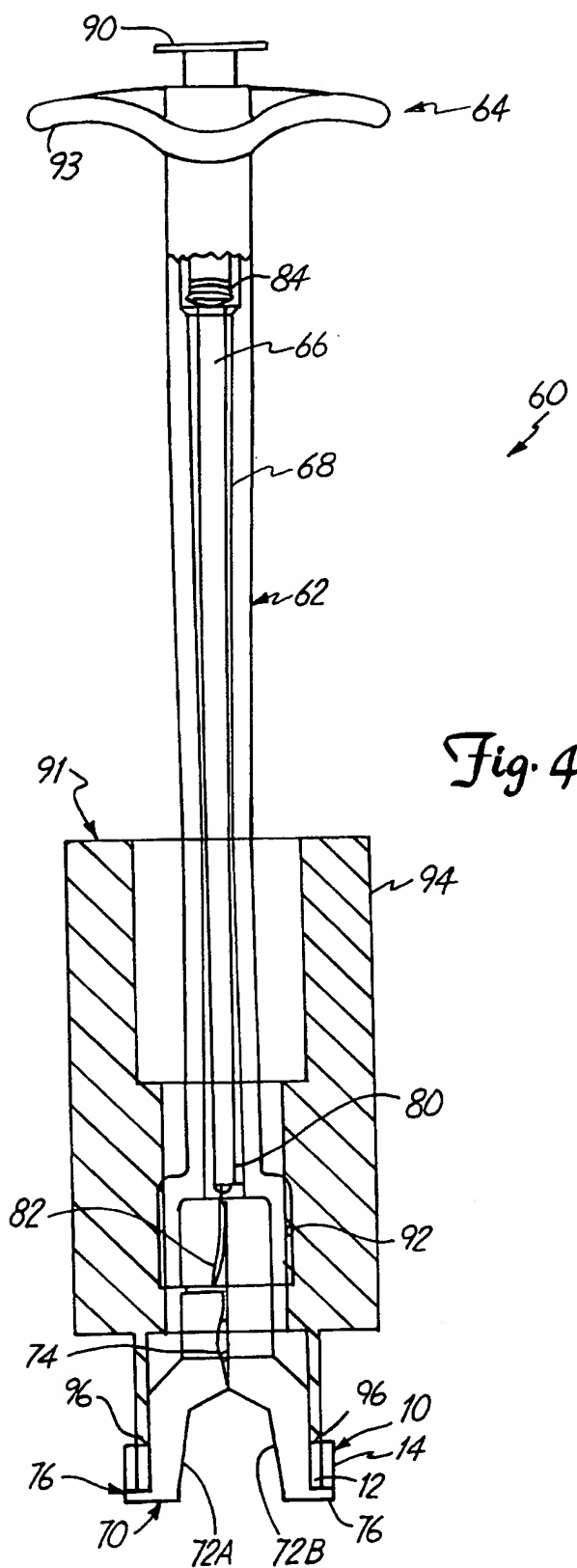
1 / 14



WO 99/53845

2 / 14

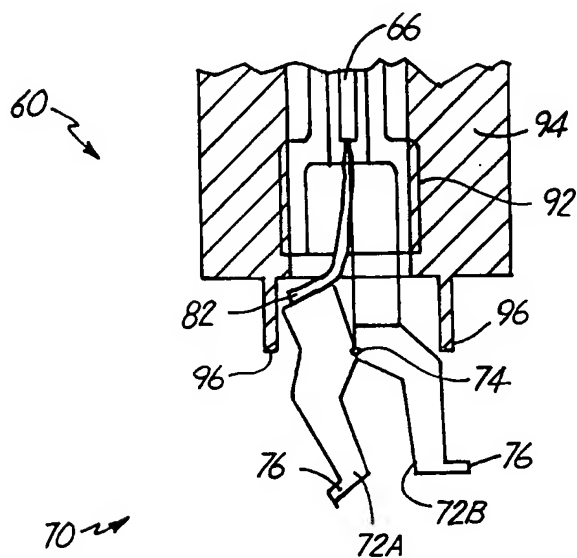
PCT/US99/08817



WO 99/53845

3 / 14

PCT/US99/08817

*Fig. 5*

WO 99/53845

4 / 14

PCT/US99/08817

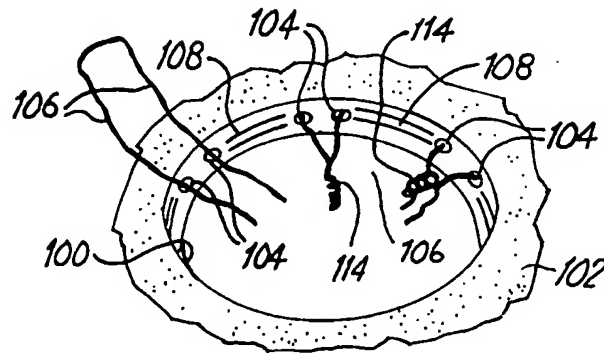


Fig. 6

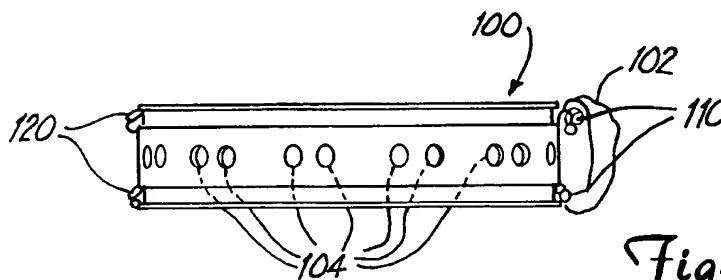


Fig. 7A

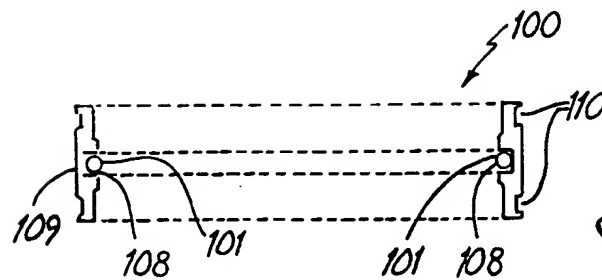


Fig. 7B

WO 99/53845

PCT/US99/08817

5 / 14

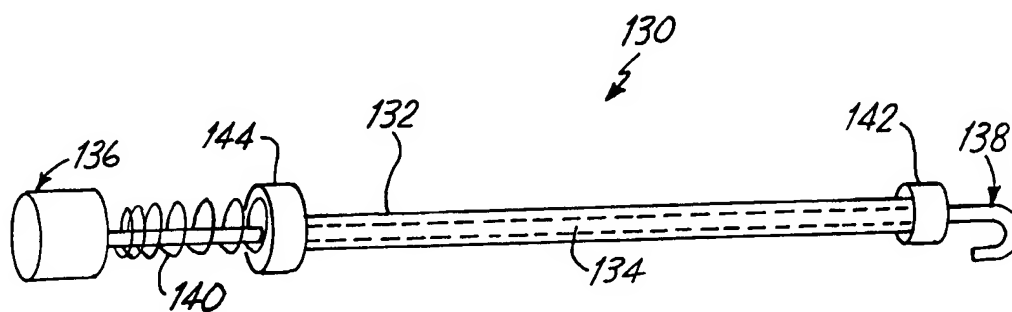


Fig. 8

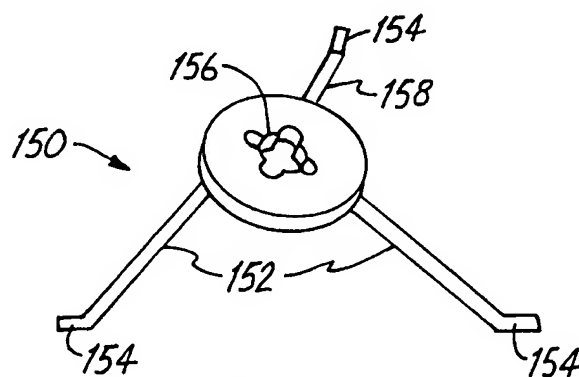
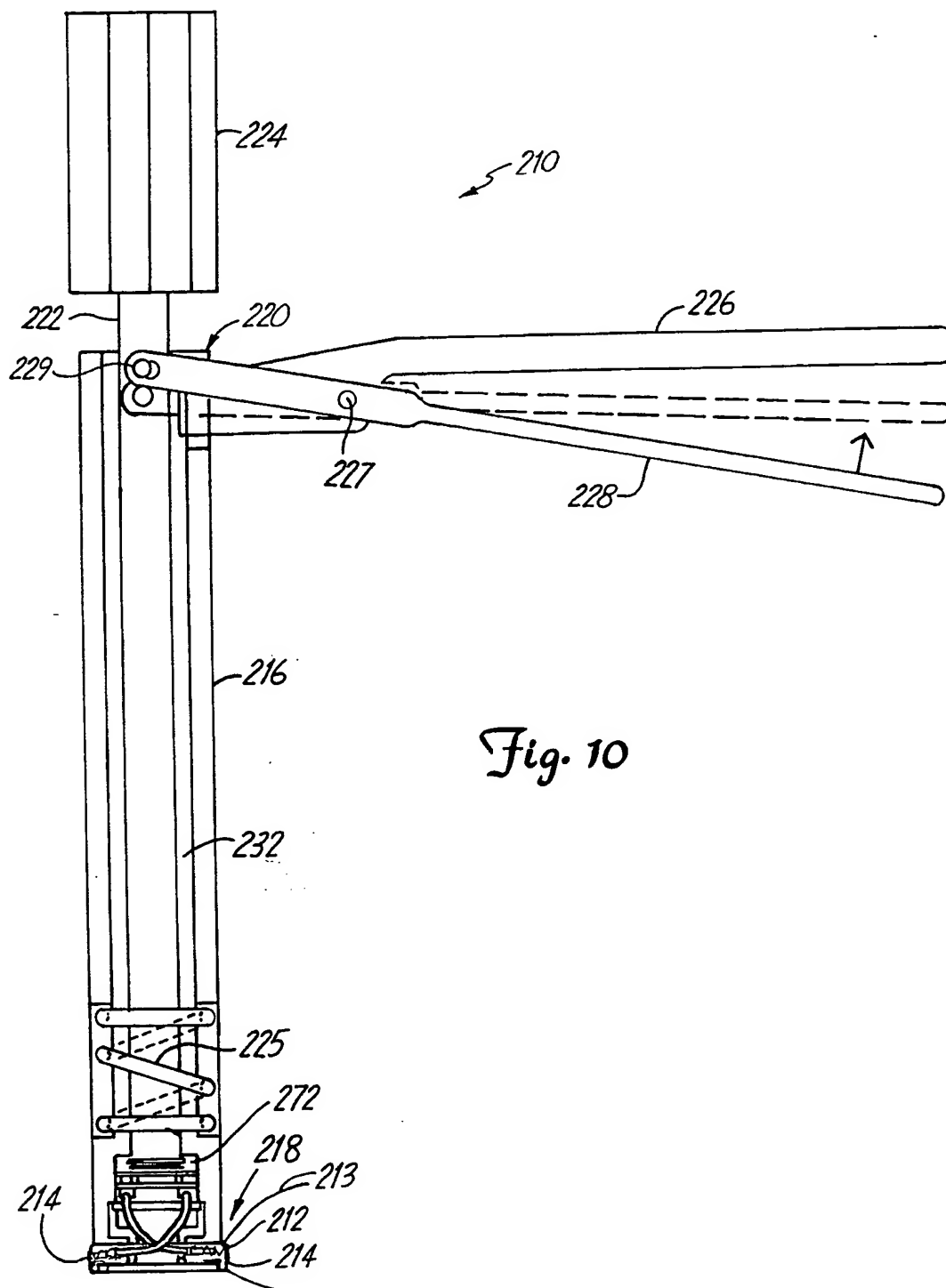


Fig. 9

WO 99/53845

PCT/US99/08817

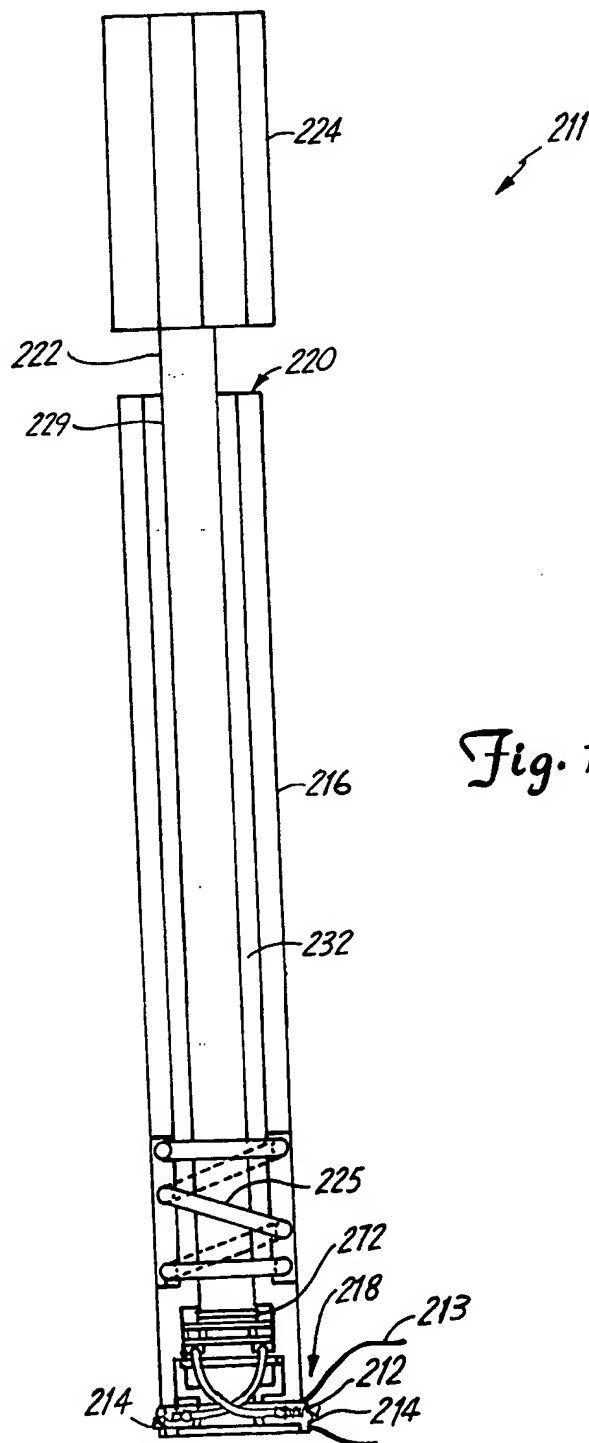
6 / 14



WO 99/53845

PCT/US99/08817

7 / 14



WO 99/53845

PCT/US99/08817

8 / 14

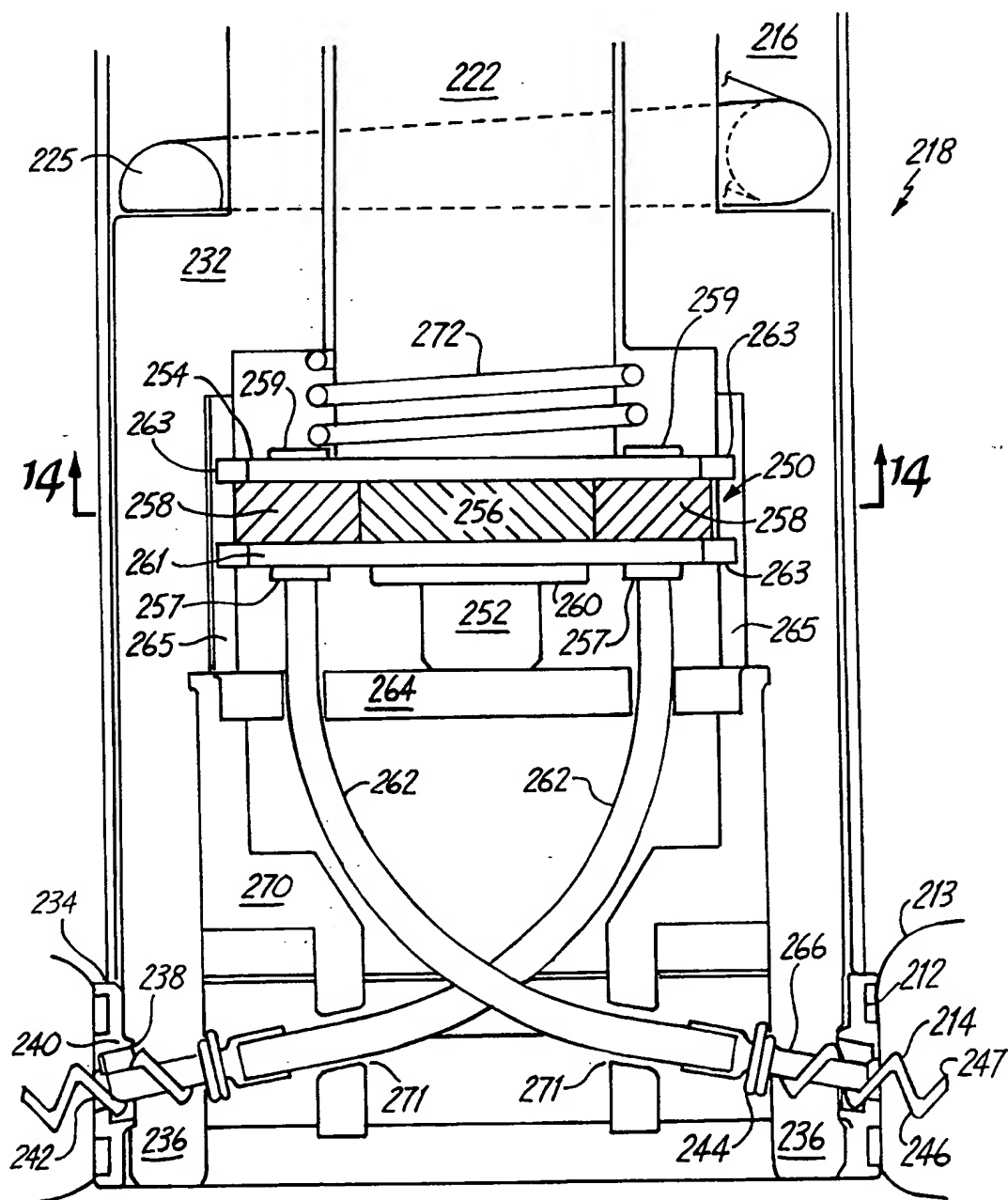
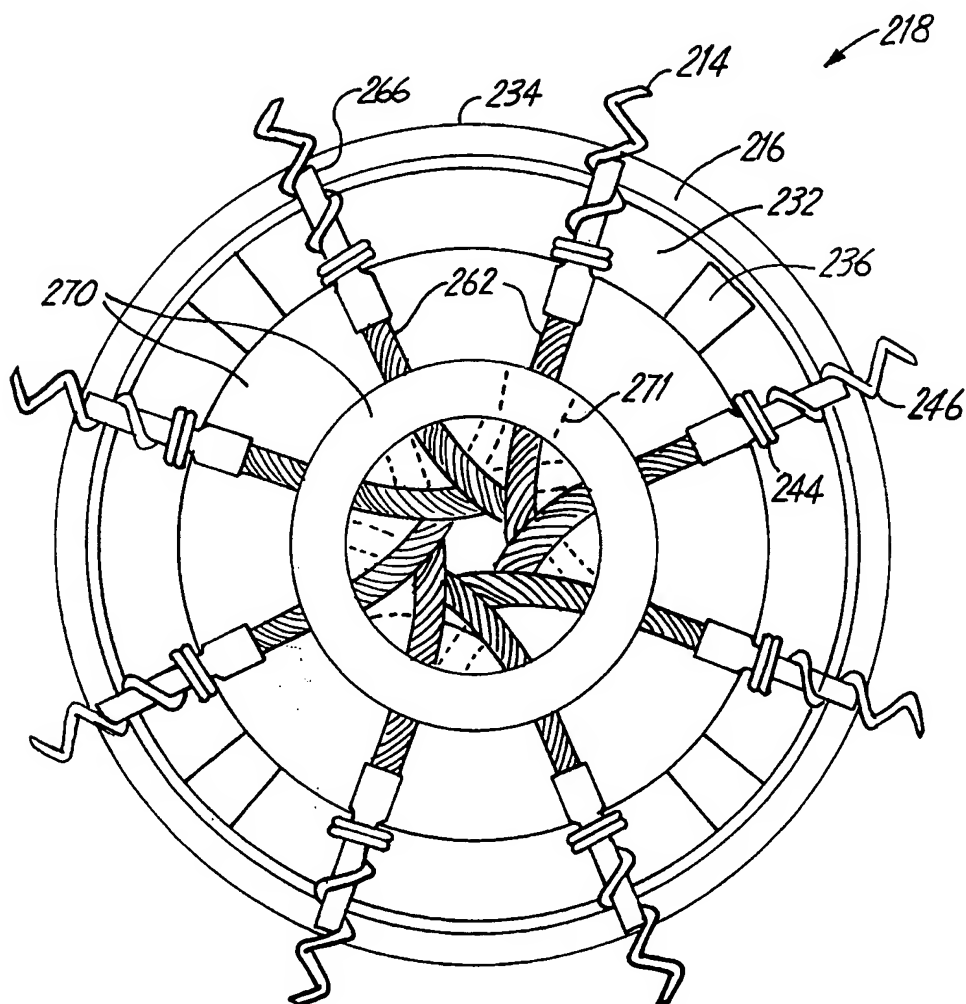


Fig. 12

WO 99/53845

PCT/US99/08817

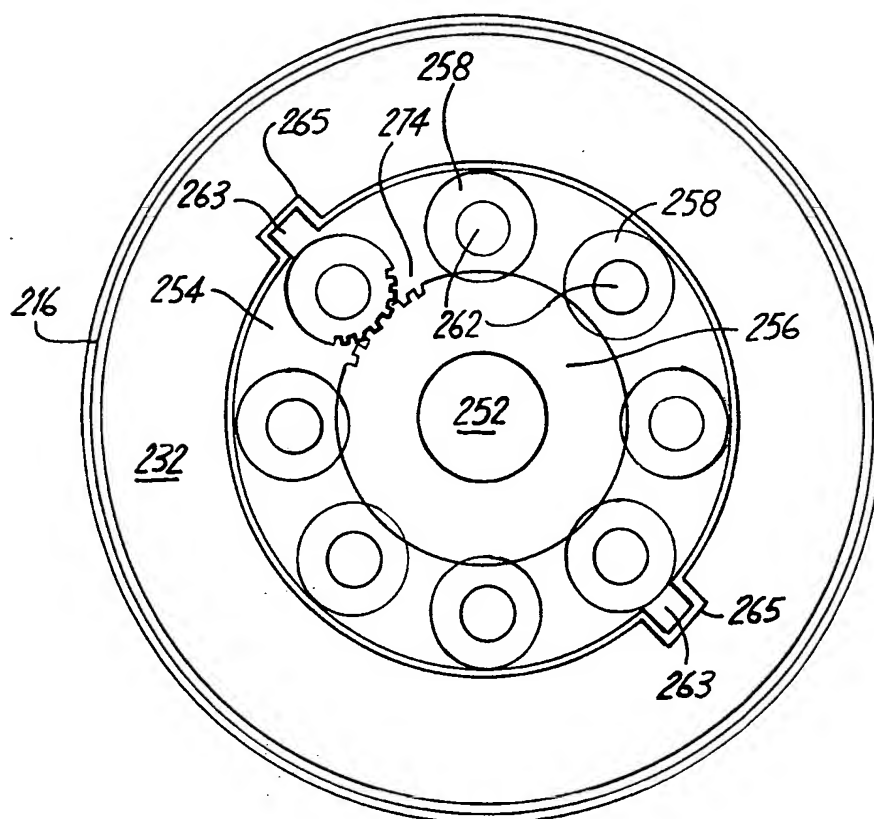
9 / 14

*Fig. 13*

WO 99/53845

PCT/US99/08817

10 / 14

*Fig. 14*

WO 99/53845

PCT/US99/08817

11 / 14

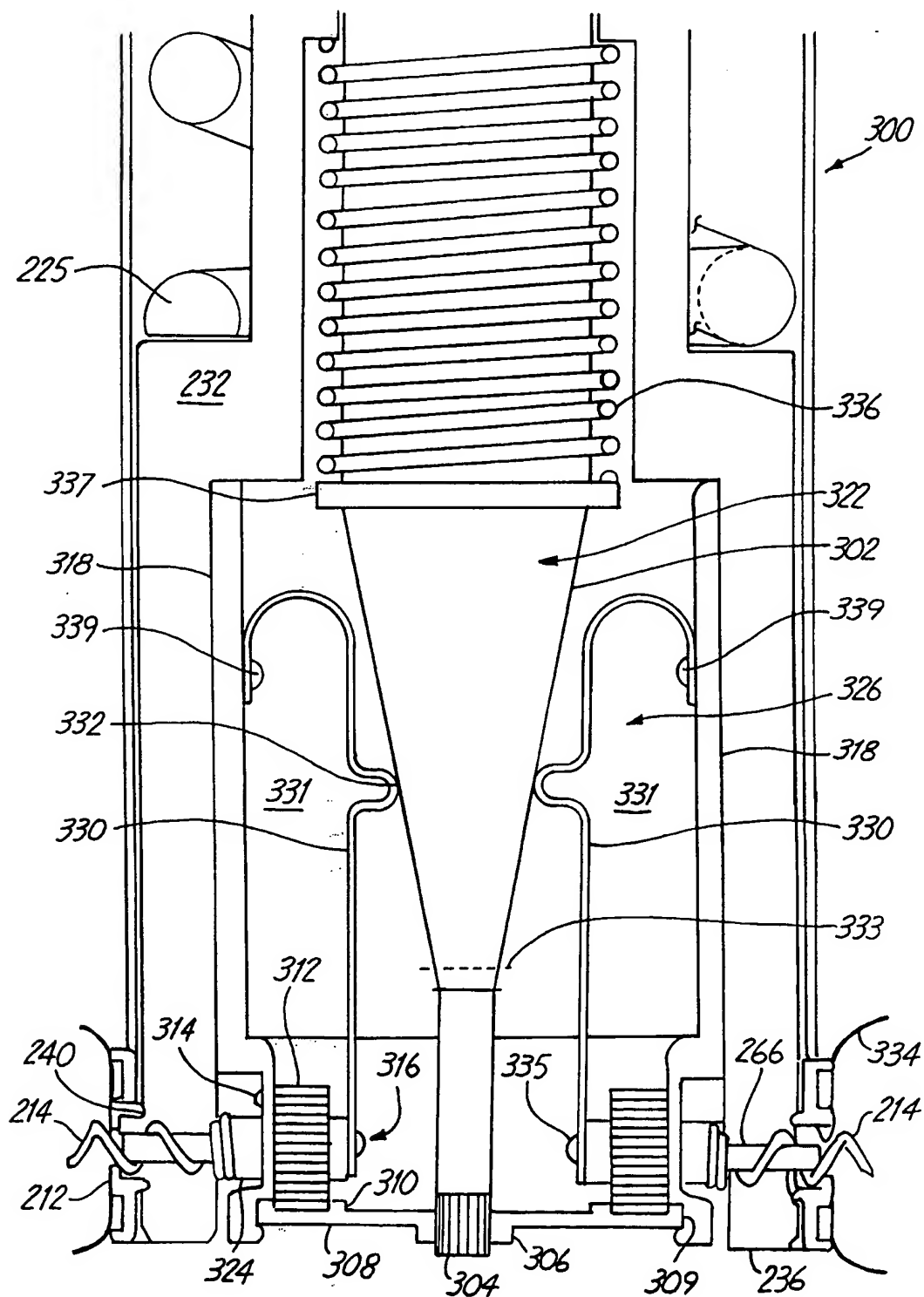
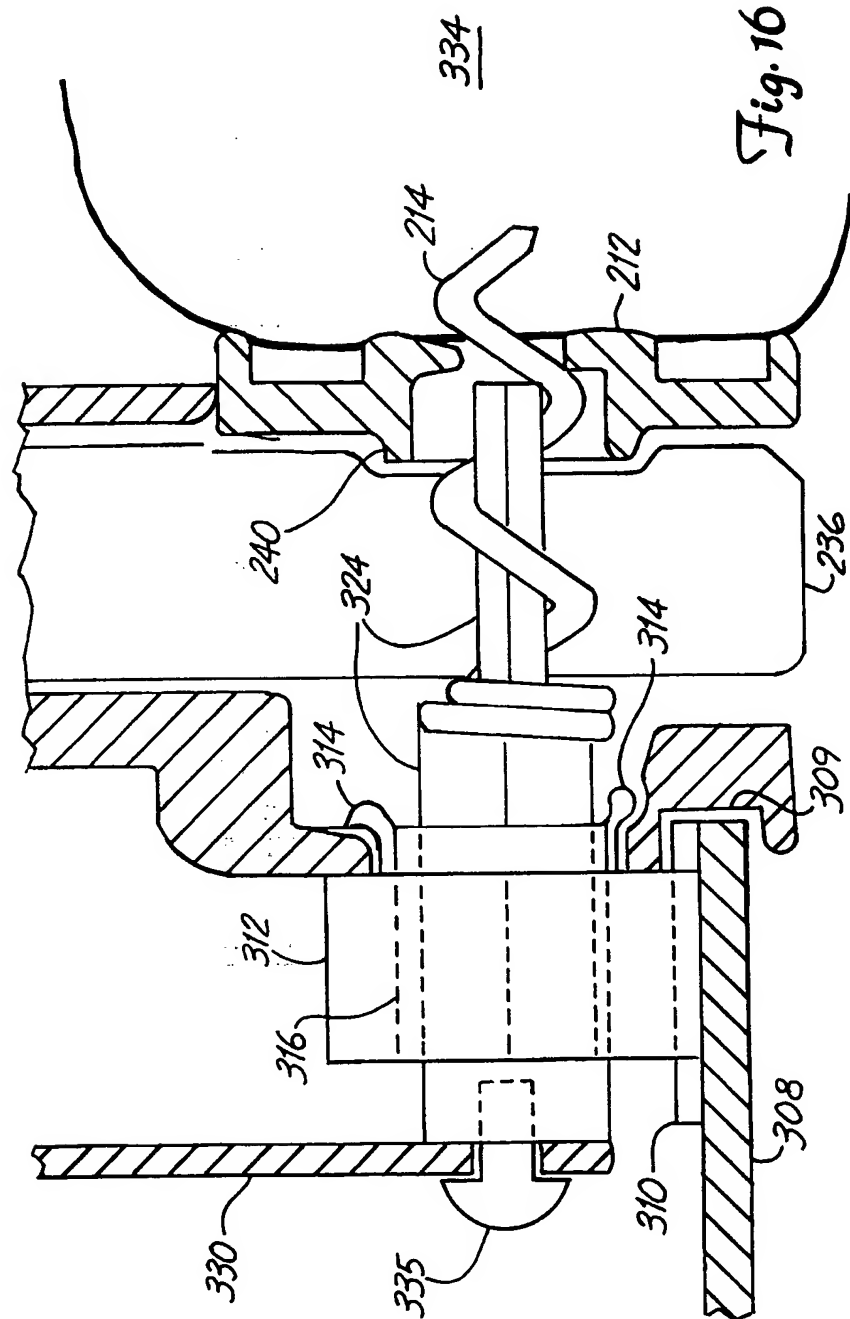


Fig. 15

WO 99/53845

PCT/US99/08817

12 / 14



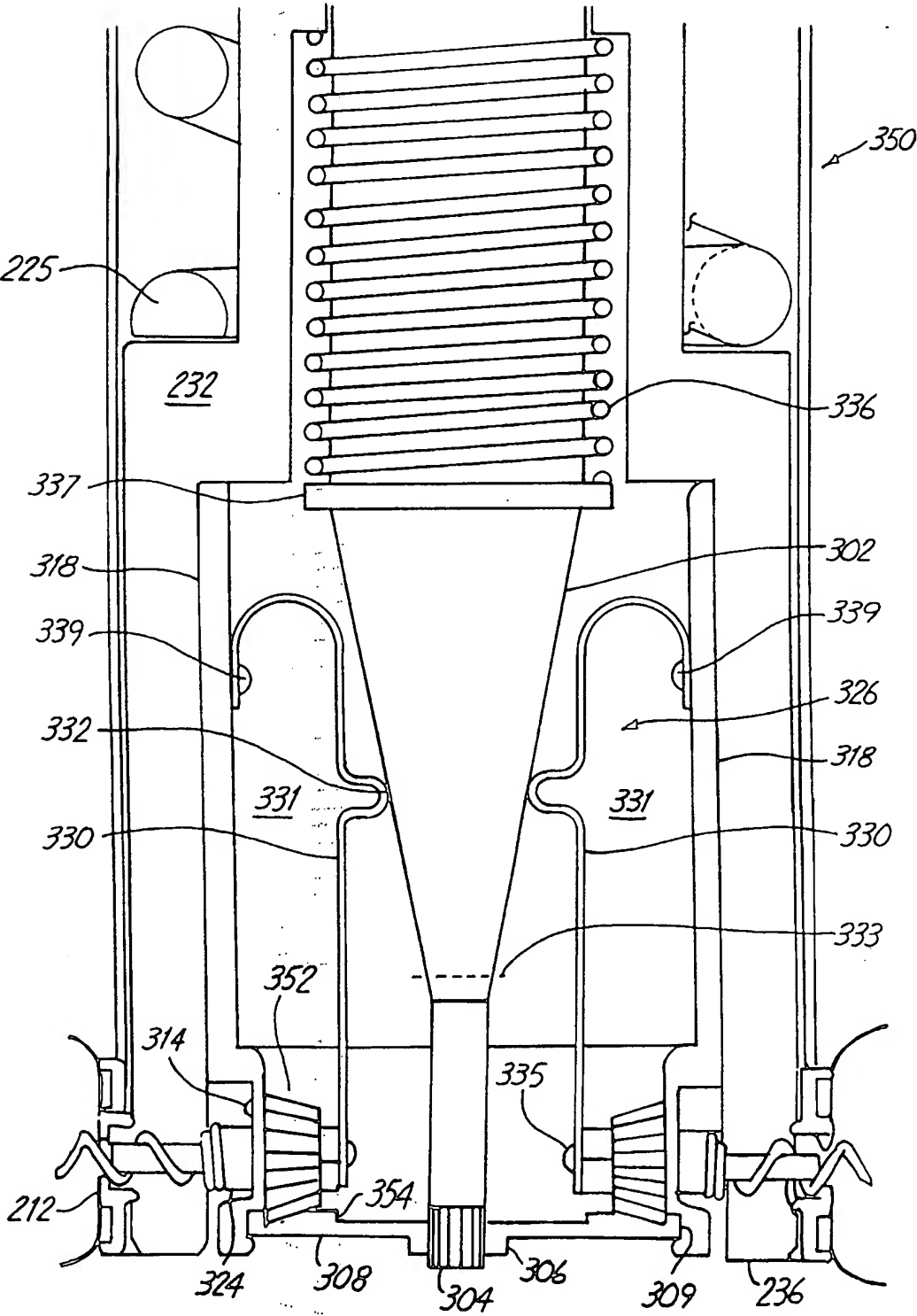
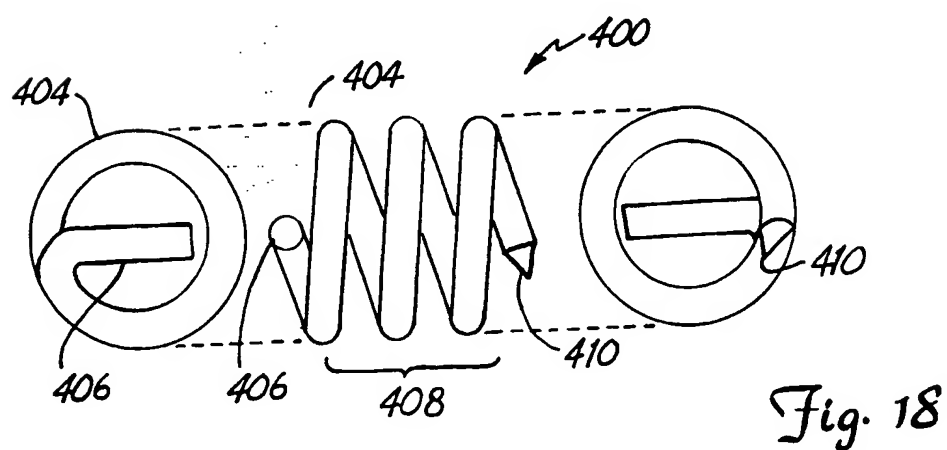
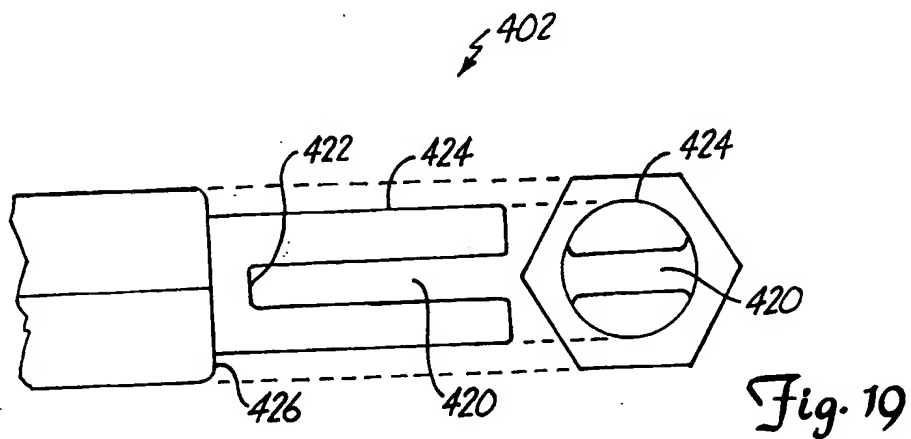


Fig. 17

WO 99/53845

PCT/US99/08817

14 / 14



INTERNATIONAL SEARCH REPORT

Intern. Application No

PCT/US 99/08817

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61B17/064 A61B17/068 A61F2/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B A61F B23P

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 97 30659 A (WILLIAMSON ET AL.) 28 August 1997 (1997-08-28) abstract; figures ---	1, 13, 15
A	US 3 686 740 A (SHILEY) 29 August 1972 (1972-08-29) abstract; figures ---	1, 13, 15
A	FR 1 386 811 A (SURGITOOL INCORPORATED) 14 May 1965 (1965-05-14) page 3, left-hand column, paragraph 2 - right-hand column, paragraph 1; figures ---	1, 13, 15
A	WO 97 09948 A (ST. JUDE MEDICAL, INC.) 20 March 1997 (1997-03-20) abstract; figures ---	1, 13, 15
	--- -/--	



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"A" document member of the same patent family

Date of the actual completion of the international search

13 August 1999

Date of mailing of the international search report

19/08/1999

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3018

Authorized officer

Giménez Burgos, R

INTERNATIONAL SEARCH REPORT

Intern	ial Application No
PCT/US 99/08817	

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 96 03925 A (ORIGIN MEDSYSTEMS, INC.) 15 February 1996 (1996-02-15) claim 1; figures ---	1, 13, 15
A	EP 0 544 102 A (BRIDGESTONE CORPORATION) 2 June 1993 (1993-06-02) -----	

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 99/08817

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 14
because they relate to subject matter not required to be searched by this Authority, namely:
RULE 39.1(IV) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 99/08817

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9730659	A	28-08-1997	US 5716370 A AU 1956297 A CA 2245771 A EP 0883387 A US 5891160 A	10-02-1998 10-09-1997 28-08-1997 16-12-1998 06-04-1999
US 3686740	A	29-08-1972	NONE	
FR 1386811	A	14-05-1965	NONE	
WO 9709948	A	20-03-1997	US 5628789 A AU 6972296 A EP 0852481 A	13-05-1997 01-04-1997 15-07-1998
WO 9603925	A	15-02-1996	US 5582616 A CA 2196905 A EP 0773742 A EP 0834282 A EP 0834283 A EP 0835641 A EP 0834284 A EP 0834285 A EP 0835642 A JP 10506026 T US 5810882 A US 5824008 A	10-12-1996 15-02-1996 21-05-1997 08-04-1998 08-04-1998 15-04-1998 08-04-1998 08-04-1998 15-04-1998 16-06-1998 22-09-1998 20-10-1998
EP 0544102	A	02-06-1993	JP 5146975 A US 5277085 A	15-06-1993 11-01-1994